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EXAMINER

RAPILLO, KRISTINE K

ART UNIT

PAPER NUMBER

3626

NOTIFICATION DATE

DELIVERY MODE

12/17/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/788,900	Applicant(s) COSENTINO ET AL.	
	Examiner KRISTINE K. RAPILLO	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 11-30, 32 and 41-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 31, 33-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/14/2005; 11/21/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3626

DETAILED ACTION

Notice to Applicant

1. This communication is in response to a Request for Continued Examination submitted May 4, 2010. Claim 1 is amended. Claim 2 is cancelled (claims 32 and 41 were previously cancelled). Claims 1—10, 31, 33 – 40 are presented for examination. Note: Claims 11 – 30, 42, 44 – 53, and 55 – 63 were previously withdrawn. In addition, Applicant cancelled withdrawn claims 43, 54, and 63.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 4, 2010 has been entered.

Claim Objections

3. Claim 3 is objected to because of the following informalities: Claim 3 is dependent upon cancelled claim 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As per claim 1, the limitation "if" is a conditional statement without corresponding "else" statements. If these limitations are not performed, then there is no defined process to be performed. The Examiner understands that in these claims, the open conditional language causes these limitations to be omitted.

Art Unit: 3626

Processes can be considered as a series of steps to achieve a claimed task. When executing a process, each step is performed. However, upon reaching an "IF-THEN-ELSE" logical block, each TRUE/FALSE option is equally likely. A process step that includes only an "IF-THEN" logical question means that "THEN" result only occurs when the answer is TRUE. An answer equally likely is FALSE and therefore the THEN result will not occur.

The Examiner takes further guidance from the MPEP § 2106(II)C on how to handle these logical blocks. Specifically, "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of the claim or claim limitation." It is the Examiner's position that when a claimed invention includes a logical block that suggests another choice (FALSE), then the resulting action is not limiting as it may never be performed.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1 and 3 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff (U.S. Patent Number 5,594,638) in view of Ohayon et al., herein after Ohayon (U.S. Patent Number 4,712,562) further in view of Brown (U.S. Publication Number 2003/0069753).

In regard to claim 1 (Currently Amended), Iliff teaches a system for determining whether a person should have health care professional attention and for providing clinical notes to a caregiver, the system comprising: a monitoring device having a microprocessor operably coupled to a memory unit (column 7, line 63), an input device (column 4, lines 39 – 49), an output device (column 4, lines 39 – 49), and a communication device (column 7, lines 49 – 62), the memory unit being programmed with a set of

Art Unit: 3626

instructions for posing questions to the person via the output device (column 6, lines 34 – 44), and, receiving answers from the person via the input device (column 6, lines 34 – 37).

Ohayon teaches a system comprising: the remote computer (Figure 1; column 3, line 56 through column 4, line 4; and column 4, lines 14 – 34) being programmed to determine whether the person should have health care professional attention based at least in part upon the answers (Figure 1; column 3, line 56 through column 4, line 27).

Brown teaches a system comprising transmitting the answers to a remote computer via the communication device (paragraph [0040] where the answers to queries are transmitted from a personal monitoring device to a computer via the web, thus the computer is remote from the device); and a remote computer programmed to: receive the answers from the monitoring device (paragraphs [0040] and [0041]); determine, for each of the questions, whether the answer to the question satisfies a condition associated with the question (Figures 5, 6A, 8, and 10); and if the answer satisfies the condition, search a datastore accessible by the remote computer for textual phrases that match the question (Figure 5 where the answer satisfies the question and additional comments related to the answer may be presented as shown in Appendix d, page 61) and automatically generate a clinical note (Figure 2; paragraphs [0044], [0105], and [0115]) containing the textual phrases (paragraph [0044]) for review by the health care professional (paragraph 41 and appendix D, page 18). The text may be customized per the script so the physician may input any type of phrase or text. The screen shot of the report shown in Appendix D, page 61 is merely an example of the type of response available.

Claim 1 is rejected under 35 U.S.C. 103 as being unpatentable over Iliff and Ohayon in view of Brown.

Iliff is directed to a computerized medical diagnostic system to assist a physician in making a patient diagnosis and provide treatment options using a computer; the patient responds to questions posed over a computer and receives responses.

Ohayon is directed to outpatient monitoring system which obtains information from the patient via a monitoring device (i.e. blood pressure cuff). The results are transmitted to a central processor for storage and analysis, and the results of the analysis are provided to the patient and/or physician.

Art Unit: 3626

Brown is directed to a remotely programmable apparatus which identifies a patient, communicates information to the patient and/or healthcare provider, and monitors the patient. The apparatus poses questions to the patient, the patient then responds and the results are transmitted to a database. A report generator displays the report, which includes both the questions and results, plus additional information that may be associated with the results.

It would have been obvious to one of ordinary skill in the art to include in the computerized medical diagnostic system of Iliff the ability to the monitor outpatients of Ohayon with the remote health monitoring system s taught by Brown since the claimed invention is merely a combination of old elements, and in the combination each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable. Ohayon and Brown provide medical monitoring systems, while Iliff provides a medical diagnostic and treatment system; it would be obvious to combine the inventions as all are directed towards the diagnosis, treatment, and monitoring of a patient electronically.

In regard to claim 3 (Original), Iliff, Ohayon, and Brown teach the system of claim 2. Iliff further teaches a system wherein the datastore also stores a symptom identifier associated with each of the questions posed to the person via the monitoring device (column 7, line 63 through column 8, line 42), wherein the remote computer is programmed to select a grammatical rule for construction of the clinical note based upon the symptom identifier (column 8, lines 27 – 28). The Examiner interprets a grammatical rule to be a system which inserts canned or pre-programmed text into a report or summary so as to link symptoms identified by the patient.

The motivation to combine the teachings of Iliff, Ohayon, and Brown is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 4 (Original), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the clinical note comprises verbiage presenting symptoms reported by the person via the input device (column 8, lines 27 – 28).

Art Unit: 3626

In regard to claim 5 (Previously Presented), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the remote computer is further programmed to generate the clinical note based upon the measurement transmitted to the remote computer (column 28, lines 19 – 34).

Ohayon teaches a system to transmit the measurement to the remote computer (column 4, line 51 through column 5, line 10); and the remote computer is further programmed to generate a clinical note based upon the measurement transmitted to the remote computer (column 4, lines 14 – 34).

Brown teaches a system wherein: the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor (paragraph [0090]) and the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient, and to transmit the measurement to the remote computer (paragraph [0090]).

The motivation to combine the teachings of Iliff, Ohayon and Brown is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 6 (Original), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the remote computer is further programmed to present a user interface that permits viewing of the clinical note and also permits viewing of a populace of persons identified as potentially needing attention by a health care professional (column 6, lines 38 – 44).

In regard to claim 7 (Previously Presented), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the remote computer communicates the clinical note to a health care professional (column 28, lines 27 - 29). Iliff fails to teach a remote computer, however, this feature is taught by Ohayon.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 through column 4, line 4 and column 4, lines 14 - 34).

Art Unit: 3626

The motivation to combine the teachings of Iliff, Ohayon, and Brown is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 8 (Previously Presented), Iliff, Ohayon, and Brown teach the system of claim 7.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 through column 4, line 4 and column 4, lines 14 - 34).

Brown teaches a system wherein the remote computer communicates the clinical note to the health care professional via e-mail (appendix: page 105).

The motivation to combine the teachings of Iliff, Ohayon, and Brown is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 9 (Original), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the remote computer is further programmed to present questions to be posed to the person using the monitoring device, the questions being used to verify the determination that the person should have health care professional attention (column 2, lines 41 – 48 and column 35, lines 33 – 42), however Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 through column 4, line 4 and column 4, lines 14 - 34).

The motivation to combine the teachings of Iliff, Ohayon, and Brown is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 10 (Original), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the remote computer is further programmed to provide a user interface (column 6, lines 38 – 44) permitting selection of a disease state for monitoring by the monitoring device (column 50, lines 53 – 58), however, however Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (column 3, line 56 through column 4, line 4).

Art Unit: 3626

The motivation to combine the teachings of Iliff, Ohayon, and Brown is discussed in the rejection of claim 1, and incorporated herein.

8. Claims 31 and 33 – 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff (U.S. Patent Number 5,594,638) and Ohayon et al., herein after Ohayon (U.S. Patent Number 4,712,562) in view of Brown (U.S. Publication Number 2003/0069753) further in view of Luttrell (U.S. Publication Number 2003/0004758 A1).

In regard to claim 31 (Previously Presented), Iliff teaches a system for determining whether a person should have health care professional attention, the system comprising: a monitoring device having a microprocessor operably coupled to a memory unit (column 7, line 63), an input device (column 4, lines 39 – 49), an output device (column 4, lines 39 – 49), and a communication device (column 7, lines 49 – 62), the memory unit being programmed with a set of instructions for posing questions to the person via the output device (column 6, lines 34 – 44), and receiving answers from the person via the input device (column 6, lines 34 – 37).

Ohayon teaches a system comprising: the remote computer (Figure 1; column 3, line 56 through column 4, line 4; and, column 4, lines 14 – 34) being programmed to; determine whether the person should have health care professional attention based at least in part upon the answers (Figure 1; column 3, line 56 through column 4, line 4; and, column 4, lines 14 – 34).

Brown teaches a system comprising: transmitting the answers to a remote computer via the communication device (paragraph [0040]); and receive the answers from the monitoring device (paragraphs [0040] and [0041]).

Luttrell discloses a system comprising: automatically create an entry in an intervention data field for the person, the entry describing a treatment to counteract a symptom experienced by the person (paragraphs 53 and 58) where automatic compilation of treatment data is created.

Claim 31 is rejected under 35 U.S.C. 103 as being unpatentable over Iliff, Ohayon, and Brown in view of Luttrell.

Art Unit: 3626

Iliff is directed to a computerized medical diagnostic system to assist a physician in making a patient diagnosis and provide treatment options using a computer; the patient responds to questions posed over a computer and receives responses.

Ohayon is directed to outpatient monitoring system which obtains information from the patient via a monitoring device (i.e. blood pressure cuff). The results are transmitted to a central processor for storage and analysis, and the results of the analysis are provided to the patient and/or physician.

Brown is directed to a remotely programmable apparatus which identifies a patient, communicates information to the patient and/or healthcare provider, and monitors the patient. The apparatus poses questions to the patient, the patient then responds and the results are transmitted to a database. A report generator displays the report, which includes both the questions and results, plus additional information that may be associated with the results.

Luttrell is directed to a method and system for recording patient treatment by progress toward identified goals. A computer allows access to and displays patient information and generates reports.

It would have been obvious to one of ordinary skill in the art to include in the computerized medical diagnostic system of Iliff the ability to the monitor outpatients of Ohayon and the remote health monitoring system as taught by Brown with the system of recording patient treatment of Luttrell since the claimed invention is merely a combination of old elements, and in the combination each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

In regard to claim 33 (Previously Presented), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 31.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 through column 4, line 27 and column 4, lines 14 - 34).

Brown teaches a system wherein the entry data further includes the date upon which the remote computer system created the entry (appendix: Figure 2, page 23).

Art Unit: 3626

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

In regard to claim 34 (Previously Presented), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 33.

Brown further teaches a system wherein the entry data further includes an indication of whether or not the treatment has counteracted the symptom (appendix: Figure 6, page 27).

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

In regard to claim 35 (Original), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 31. Iliff further teaches a system wherein the remote computer is further programmed to present a user interface that permits viewing of a populace of persons identified as potentially needing attention by a health care professional (column 6, lines 38 - 44).

In regard to claim 36 (Original), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 31. Iliff further teaches a system wherein the remote computer system is further programmed to present an operator with a set of questions, so that the operator may pose the questions to the person using the monitoring device, in response to the person having been identified as potentially needing attention by a health care professional (column 35, lines 11 - 42); wherein the set of questions are designed to permit a conclusion to be drawn regarding a diagnosis of a symptom reported by the person using the device (column 40, lines 41 - 56); and wherein the set of questions are designed to permit a conclusion to be drawn regarding selection of an intervention appropriate for the diagnosis (column 40, lines 41 - 56 and column 41, lines 46 - 62). However, Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 through column 4, line 27).

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

In regard to claim 37 (Previously Presented), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 36. Iliff further teaches a system wherein the remote computer is further programmed to arrive at a preliminary diagnosis and a preliminary intervention as a function of the person's answers to the questions posed by the operator (column 39, line 7 through column 42, line 9). However, Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 through column 4, line 27).

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

In regard to claim 38 (Previously Presented), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 37. Iliff further teaches a system wherein the remote computer is further programmed to generate a clinical note based upon the preliminary diagnosis and the preliminary intervention (column 28, lines 19 – 34). However, Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 through column 4, line 27).

Brown teaches a clinical note containing textual phrases (paragraph [0044]).

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

In regard to claim 39 (Previously Presented), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 36. Iliff teaches a system wherein the remote computer chooses the set of questions based upon the answers transmitted to the remote computer by the monitoring device (column 39, line 7 through column 42, line 9). However, Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 through column 4, line 27).

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

Art Unit: 3626

In regard to claim 40 (Previously Presented), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 36.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 through column 4, line 27).

Brown teaches a system wherein the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor (paragraph [0090]); the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient, and to transmit the measurement to the remote computer (paragraph [0090]); and the remote computer is further programmed to choose the set of questions based upon the answers transmitted to the remote computer and the measurement taken by the biometric measurement unit (paragraph [0041]).

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

Response to Arguments

9. Applicant's arguments filed May 4, 2010 have been fully considered but they are not persuasive. Applicant's arguments will be addressed herein below in the order in which they appear in the response filed May 4, 2010.

Claim Rejections Under 35 U.S.C. §103(a)

Claim 1

The Applicant argues Ohayon does not search a datastore for textual phrases that match the question and automatically generate a clinical note containing the textual phrases. The Examiner respectfully submits Brown was cited for the features above, rather than Ohayon. Brown was cited for generating a clinical note as shown in Figure 2, paragraphs 44, 105 and 115 of Brown.

Claim 31

The Applicant argues Iliff fails to teach the limitation "automatically create an entry in an intervention data field for the person, the entry describing a treatment to counteract a symptom

Art Unit: 3626

experienced by the person.” The Examiner respectfully submits that new prior art was applied to the claim, thus Applicant’s argument is moot.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is (571)270-3325. The examiner can normally be reached on Monday to Thursday 6:30 am to 3:30 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Robert Morgan can be reached on 571-272-6773. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. K. R./
Examiner, Art Unit 3626

//Neal R Sereboff//
Examiner, Art Unit 3626